REMARKS

This amendment responds to the 22 May 2003 Office communication that found Applicant's 21 April 2003 amendment non-responsive (MPEP §821.03.) This paper maintains the claims added in the 21 April 2003 submission, and re-institutes a slightly amended version of original elected claims 10-22, now appearing as claims 73-86[1]. In order to be fully responsive, this response traverses the rejections of claims 10-22 found in the Office Action mailed 29 November 2002.

A. Rejection of former claims 11, 12, 14, 15, 17, 18, 20 and 21[2] under 35 U.S.C. §112, first paragraph

The former claims cited above were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the subject matter that is stated to be not described in Applicants' specification is the step of *substantially reducing an artifact produced by aortic pulsations* in combination with other steps. The Action states that page 18 identifies aortic pulsations as an undesirable feature but does not describe how this artifact is substantially reduced.

Applicant's specification provides an example, in Figure 6D and discussed on page 29, artifacts in cardiac waveforms affected by blood moving in the great vessels (*i.e.*, the aorta and/or vena cava) in a strong magnetic field, and a clean synthetic signal produced according to a method of the claimed invention. The method is described on pages 18 and 25-27 as involving the comparison of observed signal data with training data to derive values descriptive of desired cardiac electrical features (*i.e.,* template components). The specification further describes the EKG as a construct from basis elements that can be viewed as templates (p wave, q wave, R wave, S wave, ST segment, T wave, u wave, PR segment). As an alternative to the direct

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[1] including new claim 74 having limitations based on claim 10

[2] now reinstated claims 75, 76, 78, 79, 81, 82, 84 and 85

combination of signals, which can be confounded by spurious signal deviations, a composite is constructed by computing the appropriate form of each template element and then combining them, leaving out spurious signal deviations.

In particular, the claimed invention addresses the problem of aortic artifacts coincident primarily with ST and T wave of EKG in a magnet, due to a conductor crossing magnetic field lines, called the magnetohydrodynamic effect. This source of artifact has a distant spatial origin from the electric signals generated by the heart, as do the spurious signals induced by magnetic field changes applied to the whole body. Thus, comparison of leads close to the heart will show near field differences for the heart distinct from far field differences from the aorta or from the whole body. Fitting the observed data to a template model with training data to compute weights enables distinction of these sources, such that the undesired or spurious signal from the aorta and vena cava can be isolated and eliminated from the output. The specification also describes distinct use of signal channels to identify induced voltage signals from magnetic fields of MRI vs. EKG signal channels as comparators.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

B. Rejection of former claims 10-22[3] under 35 U.S.C. §112, second paragraph

Former claims 10-22 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

The language "*that are applied to template components*" and the use of "*and/or*" was found vague. Reinstated claims 73 and 74 contain the limitations of former claim 10, amended to address the vagueness rejection. Specifically, claim 73 now positively recites a *fitting* step to address the rejection to clarify that the step is a part of the claimed method. Claim 74 removes

[3] now reinstated claims 73-86

the "and/or" from the limitation, while preserving the concept that the data generated indicates one or more cardiac events or respiratory motion.

Former claim 12 was rejected as vague due to the indefinite use of the word "it". Reinstated claim 76 is an amended version of former claim 12 that further clarifies that "it" was meant to refer to the artifact.

Former claims 13-15 were rejected as apparently incorrectly worded. Applicant thanks the Examiner for identifying this incorrect wording. Reinstated claims 77-79 are amended versions of former claims 13-15 that clarify the intended limitations therein.

Former claims 19-22 were rejected as vague for the use of the wording "*to training data*", "*which can included*", "*can represent*" and "*to a favorable comparison.*" Reinstated claims 83-86 are versions of former claims 19-22, amended to eliminate any vagueness introduced by the wording objected to by the Action.

In light of the foregoing amendments, Applicant respectfully requests reconsideration and withdrawal of these rejections.

C. Rejection of former claims 10, 16, 19 and 22[4] under 35 U.S.C. §102(b)

Former claims 10, 16, 19 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by Karlsson[5].

Claim 73, which is an amended version of former claim 10, recites:

73. *Method of performing diagnostic testing of the heart and for enhancing the clarity of a display of features of interest, relating to evaluating the health of a patient's heart under examination, comprising the steps of:*

[4] now reinstated claims 73, 80, 83 and 86

[5] U.S. Patent No. 5,819,741 issued 13 October 1998 to Karlsson, Per, *et al.*

positioning on the skin of a patient at geometrically distinct positions relative to the heart of the patient a set of electrical sensors for acquiring multivariate data of the electrical activation of said heart;

transmitting said multivariate data to a data processor;

comparing said multivariate data with training data to derive values descriptive of desired cardiac electrical features; and

fitting said values to template components to generate synthetic composite ECG electrographic data for display in an easily understood view.

The claimed invention as recited in Claim 73 (an amended version of former claim 10) comprises a method that includes a novel multivariate model of EKG signals and a technique of using training data plus multivariate data to derive a synthetic EKG from templates. Karlsson fails to teach using spatial (*multivariate*) difference information to distinguish local from distal volume current generators. Rather, Karlsson teaches a one-dimensional, point source model of the heart. This is a significant difference, not only in the method, but also in consequences. Karlsson's method essentially generates a three-lead EKG and cannot distinguish other signal sources from cardiac sources based on location/distribution of the signal generator. Unlike the presently claimed multivariate method, Karlsson's method inherently cannot distinguish local vs. distal sources of signal unless they happen to reliably have distinct temporal patterns. Such temporal patterns do not as a rule generally exist, and are clearly not the case for spurious signals attributable to external sources such as magnet resonance imaging equipment.

Additionally, Karlsson teaches application of temporal filters to eliminate artifacts that distort the EKG and fail to eliminate artifacts that are similar to the EKG. Temporal filters indiscriminately eliminate certain temporal patterns regardless of whether they were generated from the heart locally, or from a distal source such as the great vessels, or globally from the body under the influence of magnetic field gradient changes. The removal of signal that is generated by the heart distorts the EKG and is in general an undesired side effect that is unavoidable by Karlsson's method of filtering. The presently claimed invention removes spurious signals and generates cleaner synthetic signals based on *multivariate* space/location data and a multivariate model of the heart and other signals as volume current generators. This allows signal differences

from multiple chest leads to convey additional information used to derive the desired information from the heart. As discussed in the "Background" section of Applicant's specification, point source models such as Karlsson's are inaccurate and do not adequately reproduce 12-lead EKG from projections.

The presently claimed invention provides a method of concurrent multi-dimensional data collection that distinguishes local from distal signal sources that are not readily distinguishable when summed into a single net signal. It is the multi-dimensional signal characterization that captures the key distinguishing data that enables substantial elimination of the non-cardiac signals. An ability of the presently claimed invention is to eliminate magneto effects (*e.g.*, false T and/or R waves) of blood movement in aorta and veins when in or near a magnetic field, and the effects of magnetic field gradients such as occur during MRI.

The presently claimed invention builds synthetic signals from templates ("*fitting said values to template components to generate synthetic composite ECG electrographic data for display in an easily understood view*"). This eliminates spurious signals in a manner not in any way anticipated by Karlsson. The multi-dimensional (*i.e.*, multivariate) data collection and processing recited in claim 73 that enables substantial elimination of distal and global signal sources is clearly not taught by Karlsson. For at least this reason, Applicant respectfully submits that claim 73 is patentable over the cited art.

Former claims 16, 19 and 22, now reinstated claims 80, 83 and 86, all depend from independent former claim 10 (reinstated claim 73), and thus contain all the patentable limitations of claim 73. Claims 80, 83 and 86 add limitations that further narrow the invention as recited in claim 73. For at least this reason, Applicant respectfully submits that claims 80, 83 and 86 are patentable over the cited art.

D. Rejection of claims 11, 12, 14, 15, 17, 18, 20 and 21[6] under 35 U.S.C. §103(a) as being unpatentable over Karlsson

[6] now claims 74, 75,77, 78, 80, 81, 83 and 84

Former claims 11, 12, 14, 15, 17, 18, 20 and 21 (now reinstated claims 75, 76, 78, 79, 81, 82, 84 and 85) were rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson.

Former claim 11, now amended and reinstated as claim 75, depends from claim 73 and further includes the limitation of a *step of substantially reducing an artifact produced by aortic pulsations.*" As discussed above, Karlsson fails to teach a multivariate method of producing a synthetic EKG signal and distinguishing local from distal voltage sources. Aortic pulsations produce a slow rising wave of substantially similar temporal form to the T wave of the EKG. Thus, aortic pulsation signals cannot be separated from cardiac T wave by the temporal filtering methods of Karlsson. any temporal filter that eliminates the T-wave shaped aortic pulsation artifact would similarly eliminate T wave signal, distort the EKG, and hide valuable information that can report ischemia. Thus, Karlsson cannot substantially reduce such artifacts and preserve the EKG T wave without undesirably eliminating both the aortic and EKG signals. The limitation of claim 75 is understood to mean simultaneous artifact reduction and cardiac signal preservation, not total signal reduction. For at least these reasons, Applicant respectfully submits that claim 75 is patentable over the cited art.

Former claim 12, now amended and reinstated as claim 76, depends from claim 73 and further includes the limitations of analyzing the multivariate signal data to extract a respiratory baseline artifact to be subtracted from the multivariate data to minimize the effect of said artifact on said multivariate data. As discussed above, Karlsson fails to teach a multivariate method of producing a synthetic EKG signal and distinguishing local from distal voltage sources. The additional limitation of claim 76 specifies that among the templates of desired information can be included respiratory cycles in addition to QRS waves, T wave, ST segment, P wave and PR segment. Subtraction of the respiratory undulation from the EKG signal presentation is a side benefit - *extraction of respiratory cycle information* is useful in its own right. Karlsson's 0.05-100Hz and 0.5-40 Hz filters serve to eliminate signals that are not of the expected temporal form (frequency content) expected for the EKG. Karlsson does not teach *extracting respiratory cycle information* for any specific use, as opposed to the presently claimed invention that enables, for example, subtraction, as recited in claim 76, to minimize the effect of said artifact on said

multivariate data, so as to obtain a flattened baseline. For at least these reasons, Applicant respectfully submits that claim 76 is patentable over the cited art.

Former claim 14, now amended and reinstated as claim 78, depends from claim 75 and further includes the limitations of generating from said electrographic data an indicator of the timing of electrical activation of large chambers of the heart and outputting the indicator for use by legacy R-wave detectors. As discussed above, Karlsson fails to teach a multivariate method of producing a synthetic EKG signal and distinguishing local from distal voltage sources. Claim 78 indicates an advantage of substantially eliminating the aortic pulsation artifact without suppressing EKG T wave (as provided by claim 75.) False T waves added to a cardiac T wave often can attain sufficient amplitude to serve as false triggers for threshold detectors. Karlsson's temporal filter cannot reduce the total T wave height while preserving the cardiac T wave and thus obscures potentially lifesaving information about acute moment-to-moment ischemia status. For at least these reasons, Applicant respectfully submits that claim 78 is patentable over the cited art.

Former claims 15, 17, 18, 20 and 21, now reinstated claims 79, 81, 82, 84 and 85, respectively, each contain the limitations of claim 73 discussed above as patentable over the teachings of Karlsson. Thus, Applicant respectfully submits that these claims are similarly patentable over Karlsson.

E. Rejection of claims 13-15[7] under 35 U.S.C. §103(a) as being unpatentable over Karlsson in view of Snell[8] or McEachern[9]

Former claims 13-15, now amended and reinstated as claims 77-79, were rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson in view of Snell or McEachern. The

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[7] now reinstated claims 77-79

[8] U.S. Patent No. 4,791,936 issued 20 December 1988 to Snell, Jeffrey D., *et al.*

[9] U.S. Patent No. 4,094,310 issued 13 June 1978 to McEachern, Robert A., *et al.*

Action states that Karlsson discloses the claimed invention except for the step of superimposing upward spikes on the R waves, a practice taught by Snell or McEachern to allow digital marker codes or identification signals to be included in the R wave data.

Former claim 13, now amended and reinstated as claim 77, includes the patentable limitations of claim 73, plus the additional limitations of outputting to legacy R-wave detectors an indicator of the timing of electrical activation of the large chambers of the heart. Neither Snell nor McEachern supply the teaching missing from Karlsson of a multi-dimensional data acquisition and processing method as recited in claim 73. Neither reference teaches a multivariate volume generator model that distinguishes between local cardiac sources and distal sources of current and voltage.

The reliable triggering of legacy equipment recited in the present claims is patentable over the prior art because naturally occurring R waves may be attenuated or absent in various disease states, thus failing to trigger R-wave threshold trigger detectors. The method of claim 77 can assure compatibility simply by passing an indicator (*e.g.*, a spike trigger) directly to the inputs of the legacy systems that conforms in shape to the R wave voltages the legacy systems were designed to detect directly from patients. This is distinct from pacemaker triggers, which are comprised of small spikes that are visually distinct from the EKG but which are close to baseline and may not trigger legacy systems that apply threshold-dependent R wave detectors.

Furthermore, the teachings of Snell are not properly combinable with those of Karlsson. Snell's system will not function properly in the presence of a magnetic field, as opposed the presently claimed invention. Snell teaches use of telemetry from a pacemaker to report the sequence of conventional (one-dimensional) temporal events from the point of view of an internal sensor in the pacemaker, and offers conventional surface EKG signals also for comparison. The comparison is a simple visual one – a choice of data to view. It is not a computational comparison as in the presently claimed invention. Whereas the presently claimed invention specifically solves problems that occur particularly in the presence of a magnetic field (*e.g.*, during MRI), Snell is inapplicable in such a setting as it teaches the use of pacemakers.

Pacemakers are disrupted by strong magnetic fields and produce artifacts of their own and potentially life-threatening complications.

Similarly, McEachern teaches enhancing with increased intensity a display of a cathode ray tube to indicate a threshold event, plus an output to trigger cardioversion (electric shock). It does not teach an improved synthetic ECG signal based on multivariate data having an indicator output to trigger legacy R-wave detectors.

Former claims 14 and 15, now amended and reinstated as claims 78 and 79, contain all the limitations of claim 13 plus the additional aortic pulsation artifacts limitation and respiratory baseline artifact limitation of claims 75 and 76, respectively. Thus, the discussion above related to the patentibility of claims 75 and 76 is equally applicable to the discussion of the patentability of claims 78 and 79.

For at least these reasons, Applicant respectfully submits that claims 77-79 are patentable over Karlsson, Snell and McEachern.

Applicant respectfully submit that the above claims and remarks clearly establish the patentability of the claimed invention over the prior art. Favorable consideration and allowance are earnestly solicited. Should there be any questions after reviewing this paper, the examiner is invited to contact the undersigned at 617-854-4000.

Respectfully submitted,
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